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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,306	10/15/2003	Mark T. Rise	011738.00136	7914

22908 7590 10/13/2006

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EXAMINER
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KAHELIN, MICHAEL WILLIAM

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 10/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

NIT

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/687,306	RISE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Michael Kahelin	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 October 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application           |
| Paper No(s)/Mail Date <u>20050426; 20041123; 20041115</u>                              | 6) <input checked="" type="checkbox"/> Other: <u>See Continuation Sheet</u> |

Continuation of Attachment(s) 6). Other: IDS: 20040618;20040511; 20040427(X2).

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The information disclosure statement filed 11/23/2004 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because an NPL reference is lacking a date. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

### ***Claim Objections***

2. Applicant is advised that should claim 1 be found allowable, claim 24 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. In regards to claims 1 and 24, by structurally defining the monitoring component as “implanted” and the relaying module as “worn”, the claim inferentially includes the human body, which is nonstatutory subject matter, through the body’s connection to the implanted device/relaying module. It is suggested to functionally recite the components as “implantable” and “adapted to be worn”. Additionally, “a first telemetry channel” and “a second telemetry channel” are inferentially included, rendering it unclear whether these elements are actually part of the claimed invention. It is suggested to either positively recite these elements or make the record clear that these are not claimed elements.

6. In regards to claims 3 and 4, the elements are lacking a structural relationship to the other elements of the claimed invention. A system claim may not be simply a listing of parts.

7. In regards to claim 9, “the information” is inferentially included in claim 8. As it is not a positively recited element of the claimed invention, it cannot be further limited by claim 9.

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8. In regards to claim 11, “a treatment delivery unit” and “a processing unit” are inferentially included, rendering it unclear whether these elements are part of the claimed invention. It is suggested to either positively recite these elements or make the record clear that these are not claimed elements.

9. In regards to claims 13 and 14, by structurally defining the relaying module as “worn”, the claim inferentially includes the human body, which is nonstatutory subject matter, through the body’s connection to the relaying module.

10. In regards to claims 15 and 16, the claims further limit the disorder, not the system. It is suggested to claim a device adapted to treat the listed disorders.

11. In regards to claim 19, by structurally defining the treatment therapy as “provided to a location”, the claim inferentially includes the human body, which is nonstatutory subject matter, through the body’s connection to the relaying module. It is suggested to functionally recite a therapy “adapted to be provided to a location”.

12. In regards to claim 20, it is unclear how the system can both have an implanted component (as recited in claim 1) and be external (as recited in claim 20).

### ***Claim Rejections - 35 USC § 102***

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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14. Claims 1-12 and 15-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Fischell et al. (US 6,134,474, hereinafter "Fischell").

15. In regards to claims 1 and 24, Fischell discloses a system comprising an implanted component (10) that monitors a neurological signal and applies therapy, a relaying module worn by the patient (11 and 990) coupled to the implanted component by a first telemetry channel (72), and an external component (80) that communicates to the implanted component through the relaying module through a second telemetry channel (74 and 75).

16. In regards to claim 2, the system comprises a monitoring unit (36), a treatment delivery unit (40), and interfacing unit that conditions the signal, samples the signal, and activates the treatment delivery system (51, 33A-C, and 34).

17. In regards to claim 3, the implanted component comprises a monitoring element (34) and treatment delivery system (40).

18. In regards to claim 4, the device further comprises a detection algorithm (36 and abstract).

19. In regards to claims 5, 6, 8 and 9, the external component comprises a storage unit for storing information comprising output from the detection algorithm and physiological signals (col. 13, line 17).

20. In regards to claim 7, the implanted component comprises a monitoring element (21A-C), a treatment unit (412A-C), an interfacing unit that conditions the signals, samples the signals, and activates the treatment delivery unit (30 and 40), and a

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processing unit that detects events and instructs the interfacing unit to initiate therapy (51).

21. In regards to claims 10 and 11, Fischell discloses an implanted component that monitors a neurological signal and applies therapy (Fig. 25, 801D), a relaying module (982) with a first telemetry channel (811D), and an external component (990) with a second telemetry channel (992) that detects events and initiates therapy (col. 32, line 56). Further, the external device performs all functions shown in Figure 2, thus performing the functions of claim 11.

22. In regards to claim 12, the external device is a programmer (col. 13, line 22).

23. In regards to claims 15 and 16, the disorder is epilepsy, which is a CNS disorder (abstract).

24. In regards to claims 17 and 18, the therapy and neurological signals are electrical (abstract).

25. In regards to claims 19-23, treatment is provided to the brain by a hybrid system with an electrode monitoring element (Fig. 25).

### ***Claim Rejections - 35 USC § 103***

26. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.



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27. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

28. Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell. Fischell discloses the essential features of the claimed invention except for explicitly specifying that the relay module be worn on an arm or wrist of a patient. It is well known in the implantable device art to provide patient relaying modules on a patient's arm or wrist to allow the patient to wear a controlling/interface device in a manner that is comfortable, accessible, and easily seen by the patient. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Fischell's invention with a patient relaying module on the patient's arm or wrist to allow the patient to wear a controlling/interface device in a manner that is comfortable, accessible, and easily seen by the patient.

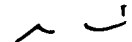
**Conclusion**

29. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Long et al. (US 6,029,084) is one of many teachings of wrist-worn relaying modules (col. 4, line 47).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
GEORGE R. EVANISKO  
PRIMARY EXAMINER

10/10/06

MWK  
  
10/6/06